

REMARKS

I) INTRODUCTION

Claims 1, 6-7, 11-15, 17-19, 22-26, 33-43, and 45-55 are now pending in the application. Claims 1, 6-7, 33-34 and 36-42 stand rejected under 35 USC § 103, claims 11-15, 17-19, 22-26, 35, 43 and 45-53 stand allowed, and claims 54-55 stand rejected under 35 USC §§ 112 and 102. The foregoing amendments and following remarks are considered by applicant overcome each of the outstanding rejections.

The Examiner is now respectfully requested by applicant to take two specific actions regarding the examination of this application. First, the Examiner is requested to withdraw each of his outstanding rejections and allow all of the claims currently pending in the application. Second, the Examiner is requested to declare an interference proceeding between claims 54-55 of the current application and US Patent 5,419,321 issued to Evans. Newly presented evidence and arguments in support of these two requests are presented below.

II) OUTSTANDING REJECTIONS

In paragraph 1 of the Office Action, the Examiner has rejected claims 54 and 55 under 35 USC § 112, first paragraph, on the basis that the claims are not supported by the specification as originally filed. In particular, the Examiner contends that the specification as originally filed does not support the language used in claims 54 and 55 relating to "living tissue" of a "patient." This rejection is respectfully traversed and believed overcome in view of the following two arguments.

First, contrary to the Examiner's position, the text "the layers of skin and fat which cover muscle tissue" on page 1, lines 22-23 of the specification does indeed encompass the "living tissue" of a "patient." This interpretation is not only supported by the direct language of the specification but is additionally supported by language contained in an article, "A New Approach to the Estimation of Body Composition: Infrared Interactance," which is cited on page 2, lines 28-31, of the specification.

Second, it is well settled that to comply with the requirements of the first paragraph of 35 USC § 112, the specification need not describe verbatim the subject matter of claims 54 and 55. So long as the specification clearly conveys to those skilled in the art information sufficient to establish inventorship in the subject matter identified in the claims, the specification will be considered to comply with this provision of US patent law. It is clear that the specification of the current application, taking into account all the information cited above, meets this standard.

For these two reasons, applicant considers claims 54 and 55 to be fully compliant with the requirements of the first paragraph of 35 USC § 112. The Examiner is therefore respectfully requested to withdraw this rejection.

In paragraph 3 of the Office Action, the Examiner has rejected claims 54 and 55 under 35 USC §102(e) as being anticipated by US Patent 5,057,695 (Hirao). This rejection is respectfully traversed by applicant and believed overcome in view of the following arguments.

Applicant respectfully points out to the Examiner that rejected claims 54 and 55, as amended and presented above, are identical to claims 1 and 2 of US Patent 5,419,321 issued to Evans. As is clearly indicated on the cover page of Evans, claims 1 and 2 recited therein have previously been found by the USPTO to be patentable over Hirao. It is therefore axiomatic that claims 54 and 55 of the present application carry the same legal presumption of validity over Hirao as do claims 1 and 2 of Evans.

Notwithstanding the foregoing, in Appendix 1 of this Amendment, applicant has provided the Examiner with a Declaration under 37 CFR §1.131. This Declaration presents evidence which establishes that Hirao does not qualify as prior art against the subject invention. Thus, in view of this Declaration, the Examiner will now be required to withdraw his outstanding anticipation rejection of claims 54 and 55.

In paragraph 5 of the Office Action, the Examiner rejects claims 1, 6, 7, 33, 34, and 36-42 under 35 USC § 103 as being unpatentable over the prior art discussed on pages 2-4 of the specification and US Patent 4,884,891 (Borsboom) in view of US Patent 3,994,602 (Howarth) and US Patent 5,057,695 (Hirao). In response to this rejection, applicant refers the Examiner to additional Declarations which are submitted under 37 CFR §1.132 and included in Appendices 2-3 of this Amendment. The Examiner's rejection is respectfully traversed and believed overcome in view of each of the attached Declarations.

As a preliminary matter, applicant again points out that the Declaration provided in Appendix 1, which was filed under 37 CFR §1.131, establishes that Hirao does not qualify as prior art against the rejected claims. Thus, the Examiner's obviousness rejection recited in paragraph 5 of the Office Action must now be withdrawn given that it was, in part, based on this reference.

Applicant has, nevertheless, submitted a second and third Declaration to provide the Examiner with further evidence establishing that the claimed invention is nonobvious over the cited references. These two Declarations are discussed in detail below.

The second Declaration, which is provided in Appendix 2 of this Amendment, was prepared by Dr. Harry Shamoon. This second Declaration presents evidence which establishes, among other things, that: (i) there has been a long felt need for a device which could accurately and noninvasively measure the blood glucose of a patient, and (ii) applicant's claimed invention solves this longstanding problem by providing unexpectedly beneficial measurements over the prior art devices.

Specifically, the evidence in Section IV of Dr. Shamoon's Declaration establishes that a previous study by the NIDDK demonstrates that by properly controlling blood glucose levels, the incidence of various complications of diabetes could be reduced by 42% to 76%. This section of the Declaration further establishes that a long felt need exists for a noninvasive blood glucose measuring device, where 95% of the results from such a device would fall within $\pm 20\%$ of the true value.

Also, the evidence in Sections V and VI of Dr. Shamoon's Declaration summarizes tests performed with both prior art single-ring devices and applicant's dual-ring device. Figures 5-6, which are described in these Sections, specifically show the results of the tests performed with the prior art single-ring devices. Figure 4, which is also described in these Sections, shows the results of tests performed with applicant's claimed dual-ring device. A comparison of these charts shows that when applicant's claimed dual-ring device is used, a significantly smaller number of measurements fall outside the $\pm 20\%$ error margin.

The third Declaration, which is provided in Appendix 3 of this Amendment, was prepared by Karl Norris who previously held the position of Director at the USDA's Agricultural Research Service Instrumentation Research Laboratory. Mr. Norris' Declaration further establishes: (i) the closest prior art in the field; (ii) that a long-standing problem existed in the prior art devices, and (iii) that applicant's claimed invention provides an unexpected beneficial solution to these problems.

First, evidence in Section III of the Norris Declaration establishes that the closest prior art devices in the field are fiber optic probes. These devices all use a single source and a single detection means. Prior art devices, such as these, have presented a long-standing problem in that they do not provide accurate measurements when the surface portion of the sample being tested is different from a deeper interior portion of the sample. In particular, these devices do not obtain two measurements of information to discriminate between regions near the surface of the sample and regions in the interior portion of the sample. This distinction is critical when the measurement of interest relates to the interior of the sample and the surface effects may be variable.

Norris further points out that, while these prior art devices may maximize the measurement volume, they do not optimize it because, among other reasons, the depth of penetration and pathlength vary simultaneously with the spacing between the source and detection means and the region near the central aperture is unduly weighted in the measurement.

Evidence in Section III of the Norris Declaration further reviews Borsboom, Hirao and Howarth in the context of the closest prior art in the field. Borsboom, according to the Norris Declaration, appears to combine a reflectometer to measure backscatter with a single ring interactance probe to measure absorption. However, Borsboom does not disclose the combining of the two measurements which will be required to solve the longstanding problem in the art discussed above. He also provides no teaching on the advantages of a full ring over his suggested

alternative use of one or four fibers.

Hirao, although not prior art, was also discussed in the Norris Declaration. According to Norris, Hirao uses a linear arrangement of a source and detection apertures to provide two optical paths. Hirao, however, does not appreciate the importance of the depth of penetration differences between the two paths. Hirao's concern is to minimize the inhomogeneity within the measurement volume to improve the reproducibility of the results. He therefore wishes to define a small measurement region by the difference between the two paths. In order to maximize the commonality of path to ensure cancellation of the common signal, and to avoid surface affects which are present near the common aperture, Hirao creates two paths whose length is much greater than the space between their end points. Hirao therefore teaches away from the use of extended apertures which would increase the size of his measurement region.

Howarth, according to the Norris Declaration, uses only one source and detection aperture for measurement of "bulk reflectance." Howarth shows that the detection window spacing should be sufficiently large so that most of the optical photon paths lie outside the boundary layer. However, contrary to the Examiner's statement on page 9 of the Office Action, Norris establishes that Howarth's "apertures are made fully diffusing so that there is no optical directionality of the light within the sample caused by the angle at which the sources or detectors are placed relative to the window." The major portion of Howarth's disclosure describes a very simple form of the prior art interactance measurement technique which provides no improvement in combination with Borsboom or the other prior art cited by applicant.

Norris indicates that the "consistency" measurement, for which Howarth does disclose a linear arrangement of a source and two detection windows, is based only on scattering and not absorption and that, in order to optimize the consistency measurement, Howarth uses a window spacing which would decrease the accuracy and precision of the bulk reflectance measurement, which depends on absorption. The only problems that Howarth defines for this scattering measurement are pitch and dirt on the windows and pulp noise. He does not suggest using two detection windows for his absorption (interactance) measurement of bulk reflectance even though he cites "it is another object of the invention to provide a gauge as above which is less sensitive to fouling of the window through which measurements are being made and also to boundary layer effects." Moreover, in his disclosure "to measure the ratio of received radiation in at least two different window locations," Howarth simply does not address the depth of penetration of the optical paths, problems of layered inhomogeneous samples, optimizing measurement volume, nonlinearity, or the other aspects of optimizing a multiple path interactance measurement which are considered by applicant.

Norris concludes that "...Borsboom does no more than disclose the basic interactance optical geometry..." and "...neither Hirao nor Howarth disclose any teaching which would lead an individual skilled in the art to the invention made by applicant."

In view of the foregoing, Section III of the Norris Declaration clearly establishes that the closest prior art known to the claimed invention, including Borsboom, Hirao, and Howarth, to the extent that these references qualify as prior art, simply did not appreciate the problem which applicant's claimed invention solves.

Second, evidence in Section IV of the Norris Declaration establishes that there has been a long-felt need for a device that would overcome the problems with the prior art devices discussed above. To reduce the effects of sample inhomogeneity, the improved device would maximize the measurement volume for a predetermined spacing and avoid preferentially measuring any region of the sample, control the effective depth from which the measurement was made in order to measure the desired stratum within the sample while reducing surface effects, define and limit the effective optical paths to reduce nonlinearity, and maximize the signal-to-noise ratio of the measurement.

Third, evidence in Section V of the Norris Declaration establishes that applicant's claimed invention provides a significant and unexpected improvement over the prior art devices described above. Norris believes that applicant's invention meets the above device criteria for fulfilling the long-felt need. In particular, this section of the Declaration verifies the findings of Dr. Shamon, and further establishes that the measurements produced by applicant's claimed invention are both superior and unexpected as compared to the prior art devices. This section of the Norris Declaration also establishes, contrary to the Examiner's statements in the third full paragraph on page 9 of the Office Action, that the geometry of the light source and detectors in applicant's claimed invention, is of functional importance.

In view of the objective evidence presented in the Declarations described above, applicant has (i) established that Hirao does not qualify as prior art against the subject application, and (ii) established that rejected claims 1, 6-7, 33-34 and 36-42 are nonobvious as compared to the cited references. The Examiner is therefore requested to withdraw his outstanding rejection under 35 USC § 103 and allow these claims based on this evidence.

III) DECLARATION OF AN INTERFERENCE

In paragraph 6 of the Office Action, the Examiner states that the interference requested in applicant's Amendment dated December 5, 1996, is not being declared. The basis for the Examiner's position is that he does not consider the interfering subject matter - claims 54 and 55 - to be patentable over Hirao. As explained above, the USPTO has previously found claims containing the same language as claims 54 and 55 to be patentably distinct from Hirao and, moreover, Hirao does not qualify as prior art against this application. The Examiner is therefore requested to reconsider this decision and declare an interference proceeding.

In paragraph 7 of the Office Action, the Examiner contends that claim 55 does not correspond substantially to claim 2 in the Evans patent as applicant previously asserted in his Amendment filed on December 5, 1995. Specifically, the Examiner contends that claim 55 is broader than claim 2 given that claim 55 does not include a limitation which requires the first and second detection means to be spaced at different distances from the emitter means. In response to the Examiner's suggestion, claim 55 has been amended such that it is now identical to claim 2 of Evans.

IV) ALLOWED CLAIMS

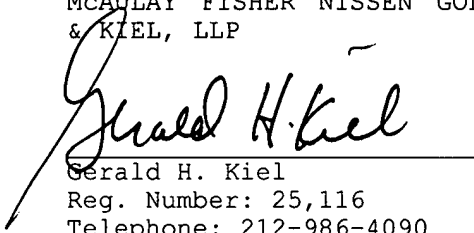
In paragraph 8 of the Office Action, the Examiner again indicates that claims 11-15, 17-19, 22-26, 35 and 53 are allowable. Additionally, in paragraph 9 of the Office Action, the Examiner indicates that claims 43 and claims 45-52 have also been allowed as a result of the Amendment we previously filed on November 10, 1995. Applicant thanks the Examiner for confirming the allowability of these claims.

Amendment Under 37 CFR §1.116
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V). CONCLUSION

In view of the foregoing discussion, the Examiner is now requested to (i) allow all of the claims currently pending in the application and (ii) declare an interference proceeding between claims 54-55 of the current application and US Patent 5,419,321 issued to Evans. A communication from the Examiner granting these two requests is earnestly solicited.

Respectfully submitted,
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